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## Declaration under Rule 4.17:

— of inventorship (Rule 4.17(iv)) for US only

## Published:

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— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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(54) Title: NEW USE FOR PHARMACEUTICAL COMPOSITION

(57) Abstract: The invention relates to the use of one or more cannabinoids in the treatment of neuropathic or chronic pain.

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/GB 03/04725A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61K31/352 A61P23/02 A61P25/20

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category <sup>o</sup>	Citation of document, with indication, where appropriate, of the relevant passages.	Relevant to claim No.
X	WO 02/064109 A (GW PHARMA LTD ;WHITTLE BRIAN (GB); GUY GEOFFREY (GB)) 22 August 2002 (2002-08-22) cited in the application page 27, line 5-15,27-33 page 28, line 15-17 page 28, line 34 -page 29, line 2 page 31, line 3-10 page 33, line 5-15 claims 26,29,45,49-53,78	1-10
P,X	GB 2 377 633 A (GW PHARMA LTD ;GW PHARMACEUTICALS LTD (GB)) 22 January 2003 (2003-01-22) page 3, line 10-13 page 19, line 5,6 claims 1-5,16,41,55,56	1-10
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 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

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- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the International search

15 April 2004

Date of mailing of the International search report

10.05.2004

Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

National Application No  
PCT/GB 03/04725

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Category	Relevant to claim No.
X	WILLIAMSON E M ET AL: "CANNABINOIDS IN CLINICAL PRACTICE" DRUGS, ADIS INTERNATIONAL LTD, AT, vol. 60, no. 6, December 2000 (2000-12), pages 1303-1314, XP001025657 ISSN: 0012-6667 * See page 1307-1308: "2.1.3, Pain relief" * ---	1-3
X	WO 02/069993 A (WERNER MICHAEL ;FORSCH HISCIA VER FUER KREBSFO (CH); JAEGGY CHRIST) 12 September 2002 (2002-09-12) page 1, line 5-10,29-31 page 2, line 10-21 page 3, line 12-15 page 7, line 38 -page 8, line 1 page 8, line 22-33 examples 1,2 page 9, line 5,6 ---	1-20
X	WO 02/080903 A (RADULOVACKI MIODRAG ;TRUSTEES OF THE UNIVERSITY OF (US); CARLEY DA) 17 October 2002 (2002-10-17) page 7, line 9-19 page 7, line 25 claims 1,5 figures 1A,1B,2A,4 ---	11-20
X	WO 02/056932 A (EMLIN BIOSCIENCES) 25 July 2002 (2002-07-25) page 4, line 4-11 page 4, line 15 claims 1,9,22,23 ---	11-20
X	DATABASE MEDLINE 'Online! US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; August 1981 (1981-08) CARLINI E A ET AL: "Hypnotic and antiepileptic effects of cannabidiol." Database accession no. NLM7028792 XP002277010 abstract & JOURNAL OF CLINICAL PHARMACOLOGY. UNITED STATES 1981 AUG-SEP, vol. 21, no. 8-9 Suppl, August 1981 (1981-08), pages 417S-427S, ISSN: 0091-2700 ---	11,12, 17,18

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

**1. Claims: 1-10**

Use of cannabinoids for the manufacture of pharmaceutical compositions for the treatment of neuropathic and chronic pain.

**2. Claims: 11-20**

Use of cannabinoids for the manufacture of pharmaceutical compositions for the treatment of sleep disturbance.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB 03/04725

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
  
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No  
PCT/GB 03/04725

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 02064109	A	22-08-2002	GB	2377633 A	22-01-2003
			GB	2381194 A	30-04-2003
			US	2002136752 A1	26-09-2002
			US	2003021752 A1	30-01-2003
			CA	2438097 A1	22-08-2002
			CZ	20032458 A3	12-11-2003
			DE	10296335 T0	15-04-2004
			EP	1361864 A2	19-11-2003
			WO	02064109 A2	22-08-2002
			GB	2380129 A	02-04-2003
			GB	2388543 A	19-11-2003
			HU	0303182 A2	29-12-2003
			NO	20033556 A	09-10-2003
GB 2377633	A	22-01-2003	CA	2438097 A1	22-08-2002
			CZ	20032458 A3	12-11-2003
			DE	10296335 T0	15-04-2004
			EP	1361864 A2	19-11-2003
			WO	02064109 A2	22-08-2002
			GB	2380129 A	02-04-2003
			GB	2388543 A	19-11-2003
			HU	0303182 A2	29-12-2003
			NO	20033556 A	09-10-2003
WO 02069993	A	12-09-2002	CA	2440070 A1	12-09-2002
			WO	02069993 A1	12-09-2002
			EP	1368048 A1	10-12-2003
WO 02080903	A	17-10-2002	CA	2443105 A1	17-10-2002
			EP	1372638 A1	02-01-2004
			WO	02080903 A1	17-10-2002
WO 02056932	A	25-07-2002	WO	02056932 A2	25-07-2002
			US	2002117175 A1	29-08-2002